REMARKS

A. Status of the Claims

Claims 1-26 are pending in the application. Claims 22-26 have been withdrawn from consideration. Claims 1-21 stand rejected. The specific grounds for rejection and Applicants' response are set forth below.

B. Objection to the Specification

The Action objects to the embedded hyperlink in the paragraph bridging pages 25 and 26 of the application. Applicants have amended this paragraph to delete the hyperlink. Applicants, therefore, request the withdrawal of this objection.

C. The Specification Adequately Describes the Subject Matter of Claims 1-21

The Action rejects claims 1-21 under 35 U.S.C. § 112, first paragraph, for lack of written description. The Action states that the claims broadly encompass a genus of antibodies that bind the *Bacillus anthracis* protective antigen, and that the specification does not place any structural limitations on the claimed antibodies. Applicants traverse this rejection.

The Federal Circuit has held that an applicant can claim an antibody by its binding affinity to a described antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004). The USPTO Guidelines provide a similar standard. In particular, Example 16 in the Synopsis of Application of Written Description Guidelines provides that a claim directed to "an isolated antibody capable of binding antigen X" would have sufficient support under 35 U.S.C. § 112, first paragraph, in a written description that disclosed "fully characterized antigens." As defined by the Federal Circuit, a "fully characterized antigen" is an antigen disclosed either by its structure, formula, chemical name, or physical properties, or by depositing the protein in a public depository. *Noelle,* 355 F.3d at 1349.

The presently claimed invention is directed to an antibody or antibody fragment that binds immunologically to *Bacillus anthracis* protective antigen. As evidenced by, for example, the Maynard *et al.* reference cited in the Action and incorporated by reference in the present application, the *Bacillus anthracis* protective antigen was known in the art and "fully characterized" at the time the present application was filed. Thus, claims 1-21 are sufficiently supported by the present disclosure.

Applicants further note that the Action fails to address the rejection of claims 9-17 for lack of written description. Claims 9-17 recite antibodies or fragments thereof comprising specific sequences. For example, claim 16 recites "The isolated antibody or fragment thereof of claim 9, further defined as comprising the variable light and variable heavy chains of SEQ ID NO:22." The Action fails to provide a basis for why the disclosure of these sequences does not provide sufficient written description for claims 9-17.

In view of the above, Applicants submit that the specification provides sufficient written description of the subject matter of claims 1-21. Applicants, therefore, request the withdrawal of this rejection.

D. Claims 1-21 Are Definite

Claims 1-21 are rejected as indefinite under 35 U.S.C. § 112, second paragraph. The Action states that the recitations "monovalent antibody portion" and "between about" are unclear. Applicants traverse these rejections.

Claims 8 and 21 contain the recitation "monovalent antibody portion." As described in claims 8 and 21, and in the specification at, for example, page 8, a monovalent antibody portion is formed from an scFv (single-chain variable region) fragment and antibody constant regions. For example, an scFv fragment could be fused to a human kappa constant region (*see*

Specification, Example 1 at page 33). Thus, Applicants submit that the meaning of "monovalent antibody portion" is clearly set forth in the specification.

In regard to the recitation "between about," Applicants submit that the cited term is sufficiently definite as one of skill in the art can readily ascertain the metes and bounds of the claim. This is demonstrated by prior case law. For example, in *Ex parte Eastwood*, 163 USPQ 316 (Bd. App. 1968), the term "about" used to define the area of the lower end of a mold as between 25 to about 45% of the mold entrance was held to be clear, but flexible. Similarly, in *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983), the court held that a limitation defining the stretch rate of a plastic as "exceeding about 10% per second" is definite because infringement could clearly be assessed through the use of a stopwatch. Here, nothing in the claims suggests that the term "about" as it is used is any less clear than the prior definite uses.

For the reasons set forth above, claims 1-21 are definite. Applicants, therefore, request the withdrawal of these rejections.

E. The Rejection Under 35 U.S.C. § 102(a) Is Overcome

The Action rejects claims 1, 4-8, and 18-21 as being anticipated under 35 U.S.C. §102(a) by Maynard *et al.* Applicants traverse this rejection.

The Action states that Maynard *et al.* teach an isolated antibody, 1H scFv, which has a K_d of 0.25 nM (250 pM). The Action further states that 1H scFv is an isolated antibody that binds immunologically to *Bacillus anthracis* protective antigen with an affinity K_d of between about 140 pM and about 21 pM as determined by surface plasmon resonance. However, claims 1-8, 12 and 18-21 recite antibodies or fragment thereof that bind immunologically to *Bacillus anthracis* protective antigen with an affinity K_d of between about **140 pM and about 21 pM** as determined by surface plasmon resonance. 250 pM is not between about 140 pM and about 21 pM. Maynard *et al.*, therefore, does not teach all of the elements of claims 1, 4-8, and 18-21.

Additionally, claims 9-11, 13-17 and 22-26 recite specific sequence identification numbers. No showing has been made that these sequences are disclosed.

In a rejection under § 102 or § 103, it is specifically required that all elements of the claims must be found in the prior art. Here, this is not the case and thus a rejection under § 102 cannot be supported. Applicants, therefore, request the withdrawal of this rejection.

F. Conclusion

In view of the above, all of the pending claims are believed to be in condition for allowance, and allowance of these claims is respectfully requested.

The Examiner is invited to contact the undersigned attorney at (512) 536-3085 with any questions, comments or suggestions relating to the referenced patent application.